

## **REMARKS**

### **Remarks**

Claim 86 is pending in the present application. Examiner is thanked for his withdrawal of prior pending 112, second paragraph rejections and 102(a) rejections. Claim 86 remains rejected under 103(a).

### **Examiner Interviews**

An interview was held with Examiners Hissong and Nickol (the Examiners) and Applicants' representatives Wilson and Farrell on December 19, 2007 to discuss the pending 103 rejection and suggested claims amendments. The Amendments and comments herein are made in view of the Interview.

### **Claim Objection**

Examiner has objected to Claim 86 stating: "it is not clear in part (a)(iii), of the recited C-terminus is the C-terminus of the ubiquitin protein, or of some other protein." Applicants disagree that the claim is unclear. However, the claim has been amended to explicitly specify that the recited C-terminus is the C-terminus of the ubiquitin protein. In view of the amendment, Applicants respectfully request that the objection be withdrawn.

### **Rejection Under 35 USC § 103(a)**

Claim 86 is rejected under 35 USC § 103(a) as being obvious in view of Vannier, *et al.*, or in view of Loosfelt, *et al.* Examiner states:

"... a person in the art, guided by the teachings of Vannier et al or Loosfelt et al, would know that ubiquitin fusion proteins can be used in methods of detecting antibodies, and thus would be motivated to create ubiquitin fusion proteins in order to practice such methods. Furthermore, the FSHR moiety of the fusion of Vannier et al could be considered to be a single epitope-containing segment, and would be expected to comprises one or more, or two or more, non-identical epitopes." Pending Action, page 4.

Examiner makes a similar argument in view of Loosfelt. In view of the comments by the Examiner above and the comments by Examiner on page 4 of the Action dated March 9, 2007

("The Examiner agrees that the protein of Vannier is unlikely to have two or more identical epitopes..." Examiner also made same comment in regards to the protein of Loosfelt) Applicants have amended the pending claim to remove references to "non-identical epitopes" from the claim. In view of the amendment, Applicants submit that the pending rejection has been overcome and requests that the rejection be withdrawn.

During the Interview held on December 19, 2007 with the Examiners, Examiner Nickol suggested that proteins may exist that can be linked to ubiquitin consistent with the teachings of the present claimed invention. He indicated that this would be difficult to determine without a working definition of "epitope." In view of this concern, Applicants submit definitions of epitope as understood by those practiced in the art and submit that the term "epitope" in the present invention is defined as:

**"EPITOPE - As related to protein antigens, B-cell epitopes consist of the amino acid residues of a protein molecule which interact directly through noncovalent bonds with the amino acid residues of a particular antibody molecule (complementarity determining region). The average epitope probably involves about 15-20 contact amino acid residues, but one or two of these may be critical to the epitope's specificity and the avidity of the antibody-antigen reaction. B-cell epitopes may be either *linear* or *conformational* in nature. T-cell epitopes represent the small, processed peptides which bind to MHC class I and II molecules on the surface of T cells." Emphasis added.**

<http://www.med.unc.edu/wrkunits/3ctrpgm/pmbb/mbt/GLOS.htm>

and; DeLisser defines an epitope as consisting "of 15-22 residues, with 5-6 residues contributing most of the binding energy" (Adhesion Protein Protocols, Vol. 96:11-20, February 1999).

In view of the arguments made above, Applicants submit that Loosfelt and Vannier do not teach the ubiquitin fusion proteins of the present invention. A finding of obviousness requires the teaching of each element of the claimed invention in the prior art. MPEP 2143. Vannier and Loosfelt do not teach all of the elements of the present invention alone or in combination. As can be seen from the limitations of the pending claim, the fusion proteins of the instant invention are not typical of the types used in the art at the time of the invention. Applicants submit that it was unknown in the art at the time of the invention and filing of the application that the fusion proteins of the present invention would be effective in the detection of antibodies since the fusion proteins of the instant invention are made at ubiquitin sites (e.g., at

the N-terminus, internally or non-cleavable C-terminus) not typically used and with proteins not found natively (e.g., with multiple identical epitopes).

Applicants believe that their arguments successfully overcome the Examiners' rejection and respectfully request that the pending rejection be withdrawn and the claim passed to allowance.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 500282.

Respectfully submitted,



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Date:

12/19/07

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